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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,128	03/15/2004	Bradley J. Glenn	04005.101	3404

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EXAMINER

BLANCO, JAVIER G

ART UNIT PAPER NUMBER

3738

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	Application No. 10/802,128	Applicant(s) GLENN ET AL.	
	Examiner Javier G. Blanco	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 4-6,8,9,13,16 and 18-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,7,10-12,14,15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of INVENTION I: intervertebral implant (claims 1-22), and Species C (embodied in Figures 17-19) in the reply filed on September 26, 2006 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 4-6, 8, 9, 13, 16, and 18-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 26, 2006.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 14, 15, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Regarding claim 14, the limitation "after discharge from the cannula and transition of said helical spring from said martensite phase to said austenite phase" (see lines 4-6) is indefinite as to the scope of the invention. The limitation apparently indicates that the helical spring will be "elongated along said center line and decreased in diameter away from said center line" after

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being discharged from the cannula. Also, the limitation “decreased away from said center line” is vague and confusing, rendering said limitation indefinite as to the scope of the invention. The Examiner will broadly interpret this claim as a spring made from a shape-memory or shape-retaining material (e.g., nickel and/or titanium alloys).

b. Regarding claim 15, “said turns adjacent a middle of said spring” (see line 1) lacks antecedent basis.

c. Regarding claim 17, the limitation “somewhat elliptical” is indefinite. Said limitation is not positively claiming the outline as elliptical.

d. Regarding claim 17, the limitation “said turns have said turn height” lacks antecedent basis.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 7, 10-12, 14, 15, and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Steffen (DE 101 30 825 A1).

Referring to Figure 1, Steffen discloses an implant comprising a helical spring (shape memory spiral 3) having a plurality of turns about a *substantially* linear center-line. A turn height

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of said spring is *substantially* similar to a height of a space between two vertebrae. A “height” could arbitrarily be any height within the space between two vertebrae. Also, it should be noted that “a height of a space between two vertebrae” varies according to patient’s age and/or condition. Said helical spring is *substantially* barrel-shaped (i.e., *substantially* ellipsoidal) with ends of said helical spring shorter in height than a middle portion of said helical spring.

7. Claims 1-3 and 14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lin (US 5,716,416 A).

Referring to Figures 1B and 1C, Lin discloses an implant (implant 100) comprising a helical spring (see inner spring shown in Figures 1B and 1C) having a plurality of turns about a center-line, which center-line is substantially linear when said helical spring is located within the cannula/endoscope/tool 300/500. A turn height of said spring is *substantially* similar to a height of a space between two vertebrae (see Figures). A “height” could arbitrarily be any height within the space between two vertebrae. Also, it should be noted that “a height of a space between two vertebrae” varies according to patient’s age and/or condition. Said helical spring is made of a shape-retaining titanium-base material, or an alloy material made of cobalt, molybdenum, and nickel (see column 2, lines 51-57).

8. Claims 1-3 and 14 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Fehling et al. (US 6,770,094 B2).

Referring to Figure 1, Fehling et al. disclose an implant comprising a helical spring (spring 16) having a plurality of turns about a center-line, which center-line is substantially linear. A turn height of said spring is *substantially* similar to a height of a space between two vertebrae (see Figures). A “height” could arbitrarily be any height within the space between two

vertebrae. Also, it should be noted that "a height of a space between two vertebrae" varies according to patient's age and/or condition. Said helical spring is made of a shape memory alloy (SMA's such as Nitinol).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:


- a. Studer et al. (WO 2004/084774 A1): see Figures 4, 5, 7, and 8.
- b. Heneveld (US 2006/0155379 A1): see Figures 7-9.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

October 14, 2006



David H. Willse
Primary Examiner